

manufacturing of a blood product becomes an active ingredient or a finished dosage form of such product.

(h) *Advertising* and *labeling* include the promotional material described in § 202.1(l) (1) and (2) of this chapter, respectively.

(i) The definitions and interpretations contained in sections 201 and 510 of the act shall be applicable to such terms when used in this part 607.

[40 FR 52788, Nov. 12, 1975, as amended at 55 FR 11014, Mar. 26, 1990]

**§ 607.7 Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products.**

(a) All owners or operators of establishments that engage in the manufacturing of blood products are required to register, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act. Registration and listing of blood products shall comply with this part. Registration does not permit any blood bank or similar establishment to ship blood products in interstate commerce.

(b) Forms for registration of an establishment are obtainable on request from the Center for Biologics Evaluation and Research (HFB-240), 8800 Rockville Pike, Bethesda, MD 20892 or at any of the Food and Drug Administration district offices.

(c) The completed form should be mailed to the Center for Biologics Evaluation and Research (HFB-240), 8800 Rockville Pike, Bethesda, MD 20892.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11014, Mar. 26, 1990]

**Subpart B—Procedures for Domestic Blood Product Establishments**

**§ 607.20 Who must register and submit a blood product list.**

(a) Owners or operators of all establishments, not exempt under section 510(g) of the act or subpart D of this part 607, that engage in the manufacture of blood products are required to register and to submit a list of every blood product in commercial distribution (except that listing information

may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments), whether or not the output of such blood product establishment or any particular blood product so listed enters interstate commerce.

(b) Preparatory to engaging in the manufacture of blood products, owners or operators of establishments who are submitting an establishment license application to manufacture blood products are required to register before the establishment license application is approved.

(c) No registration fee is required. Establishment registration and blood product listing do not constitute an admission or agreement or determination that a blood product is a “drug” within the meaning of section 201(g) of the act.

**§ 607.21 Times for establishment registration and blood product listing.**

The owner or operator of an establishment entering into an operation defined in § 607.3(d) shall register such establishment within 5 days after the beginning of such operation and submit a list of every blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation (defined in § 607.3(d)) for which a license is required, registration shall follow within 5 days after the submission of an establishment and product license application in order to manufacture blood products. Owners or operators of all establishments so engaged shall register annually between November 15 and December 31 and shall update their blood product listing information every June and December.

**§ 607.22 How and where to register establishments and list blood products.**

(a) The first registration of an establishment shall be on Form FD-2830 (Blood Establishment Registration and Product Listing) obtainable on request from the Department of Health and Human Services, Food and Drug Administration, Center for Biologics